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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR                | ATTORNEY DOCKET NO.   | CONFIRMATION NO. |
|--|-------------|-------------------------------------|-----------------------|------------------|
| 10/517,509   | 06/13/2005  | Herman Jan Tijimen Coelingh Bennink | 0470-045922           | 1291             |
| 28289 7590 10/15/2007<br>THE WEBB LAW FIRM, P.C.<br>700 KOPPERS BUILDING |             |                                     | EXAMINER              |                  |
|  |             |                                     | JEAN-LOUIS, SAMIRA JM |                  |
| 436 SEVENTH AVENUE<br>PITTSBURGH, PA 15219                               |             |                                     | ART UNIT              | PAPER NUMBER     |
|  | •           |                                     | 4173                  |                  |
|  |             |                                     |                       |                  |
|  |             |                                     | MAIL DATE             | DELIVERY MODE    |
|  |             |                                     | 10/15/2007            | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|  | Application No.  | Applicant(s)  |  |  |  |
|--|--|---|--|--|--|
|  | 10/517,509   | COELINGH BENNINK ET AL.   |  |  |  |
| Office Action Summary  | Examiner   | Art Unit  |  |  |  |
|  | Samira Jean-Louis  | 4173  |  |  |  |
| The MAILING DATE of this communication app<br>Period for Reply   | ears on the cover sheet with the c   | orrespondence address   |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).   | ATE OF THIS COMMUNICATION<br>36(a). In no event, however, may a reply be time<br>will apply and will expire SIX (6) MONTHS from<br>cause the application to become ABANDONE! | N. the mailing date of this communication. D (35 U.S.C. § 133). |  |  |  |
| Status   |  |   |  |  |  |
| Responsive to communication(s) filed on  2a) ☐ This action is <b>FINAL</b> . 2b) ☑ This  3) ☐ Since this application is in condition for allowan closed in accordance with the practice under E  | action is non-final.<br>nce except for formal matters, pro   |   |  |  |  |
| Disposition of Claims  |  |   |  |  |  |
| 4)  Claim(s) 17-32 is/are pending in the application 4a) Of the above claim(s) is/are withdraw 5)  Claim(s) is/are allowed. 6)  Claim(s) is/are rejected. 7)  Claim(s) is/are objected to. 8)  Claim(s) 17-32 are subject to restriction and/or  | vn from consideration.   |   |  |  |  |
| Application Papers   |  |   |  |  |  |
| 9) The specification is objected to by the Examiner 10) The drawing(s) filed on is/are: a) access Applicant may not request that any objection to the of Replacement drawing sheet(s) including the correction in the original of the correction and the correction is objected to by the Examiner of the correction is objected to by the Examiner of the correction is objected to by the Examiner of the correction of the correc | epted or b) objected to by the Edrawing(s) be held in abeyance. See on is required if the drawing(s) is obj  | e 37 CFR 1.85(a).<br>ected to. See 37 CFR 1.121(d).             |  |  |  |
| Priority under 35 U.S.C. § 119   |  |   |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:  1. Certified copies of the priority documents have been received.  2. Certified copies of the priority documents have been received in Application No  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.  |  |   |  |  |  |
| Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date   | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal Pa  | te  |  |  |  |

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## **DETAILED ACTION**

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## Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

- I. Group I, claims 17-27 are drawn to a cosmetic method of treating human skin by delivering an estrogenic component to said skin, the method comprising applying to the skin a composition containing an estrogenic component and a cosmetically acceptable vehicle.
- II. Group II, claim 28 is drawn to a method of treating or preventing vaginal dryness comprising applying to the vaginal epithelium a composition containing an estrogenic component and a cosmetically acceptable vehicle.
- III. Group III, claim 29 is drawn to a method of promoting wound healing comprising applying to the wounded tissue or to tissue in the vicinity of the wound a composition containing an estrogenic component and a cosmetically acceptable vehicle.

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- IV. Group IV, claim 30 is drawn to a method of treating or preventing acne comprising applying to the skin affected by acne or that is at risk of being affected by acne a composition containing an estrogenic component and a cosmetically acceptable vehicle.
- V. Group V, claims 31-32 are drawn to a skin care composition for topical administration containing an estrogenic component and a cosmetically acceptable vehicle.

The inventions listed as Groups I, II, III, IV, and V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features.

An international application should relate to only one invention or, if there is more than one invention, the inclusion of those inventions in one international application is only permitted if all inventions are so linked as to form a single general inventive concept (PCT Rule 13.1). With respect to a group of inventions claimed in an international application, unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features.

The expression "special technical features" is defined in PCT Rule 13.2 as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art. The determination is made

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on the contents of the claims as interpreted in light of the description and drawings.

Whether or not any specific technical feature makes a "contribution" over the prior art, and therefore constitutes a "special technical feature", should be considered with respect to novelty and inventive step.

In this instant application, the common technical feature in all groups is the skin care composition containing an estrogenic component and a cosmetically acceptable vehicle. This composition cannot be said to be a special technical feature under PCT Rule 13.2 because this composition is shown in the prior art.

In this case, Shah (Shah, Am. J. Clin. Dermatol. 2001, Vol. 3, No. 2 pgs. 143-150, already cited by applicant and filed with a 1449 IDS) disclosed the use of percutaneous estradiol gel in the art (inherently containing thickeners that are cosmetically acceptable vehicles) and its subsequent effects on skin thickness (see page 145, column 1, lines 4-7). As a result, no special technical features exist among the different groups because the inventions in Groups I-V fail to make a contribution over the prior art with respect to novelty and inventive step. In conclusion, there is a lack of unity of inventions, and therefore restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims.

Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise

an allowable product claim for that process invention to be rejoined.

require all the limitations of the allowable product claim will be considered for rejoinder.

<u>All</u> claims directed to a nonelected process invention must require all the limitations of

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In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is further reminded that upon the cancellation of claims to a nonelected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be Application/Control Number: 10/517,509

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accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR

1.17(i).

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Samira Jean-Louis whose telephone number is 571-

270-3503. The examiner can normally be reached on 7:30-5 PM EST M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone

number for the organization where this application or proceeding is assigned is 571-

273-8300.

Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SJL

10/10/07

ARDIN H. MARSCHEL

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COLERA SORY PATENT EXAMINER